

Applicants: Arlindo L. Castelhana, et al.
Serial No.: 09/728,616
Filed : December 1, 2000
Page 24

Remarks

Claims 76-102, 110, 114-124, 128-131 and 133-135 were pending in the subject application. By this amendment applicants have amended claim 117. Accordingly, claims 76-102, 110, 114-124, 128-131 and 133-135 are currently pending.

Support for the amended claim 117 is provided in the specification, inter alia, at page 13, lines 22-27 and page 14, lines 16-20.

Double Patenting - Claim 99

On pages 2-4 of the January 27, 2005 Office Action, the Examiner rejected claim 99 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1, 4-6 U.S. Patent No. 6,686,366 ("the '366 patent"). The Examiner alleged that although the conflicting claims are not identical, they are not patentably distinct from each other because the Markush groups of both claim sets comprise a compound of the same structure.

In response to applicants' remarks in their October 28, 2004 Amendment the Examiner alleges that the '366 patent "encompasses" the identical compound as set forth in claim 99 of the instant application. The Examiner alleges that one of skill in the art would have found it obvious to select any of the compound of the genus of the '366 patent and use it as an adenosine A3 agonist, as the '366 patent discloses the use of the claimed compounds in various methods of use.

Applicants maintain that the compound claimed in claim 99 is a later-filed improvement over the compounds claimed in the '366 patent. "The fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound

Applicants: Arlindo L. Castelhana, et al.
Serial No.: 09/728,616
Filed : December 1, 2000
Page 25

obvious." In re Baird, 16 F.3d 380, 382 (Fed. Cir. 1994)

The analysis employed in an obviousness-type double patenting determination must parallel the guidelines for a 35 U.S.C. §103(a) rejection, i.e., the factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1 (1966): a) the scope and content of '366 patent claims 1 and 4-6 relative to claim 99 in the application at issue; b) the differences between the scope and content of '366 patent claims 1 and 4-6 as determined in a) and claim 99 in the application at issue; c) the level of ordinary skill in the pertinent art; and d) any objective indicia of nonobviousness.

Claims 1 and 4-6 of the '366 patent recite a genus of A3 receptor antagonist compounds. This genus was first disclosed in PCT International Application No. PCT/US99/12135, filed June 1, 1999. Thus, the genus claimed in '366 patent claims 1 and 4-6 is entitled to the priority date of the PCT International application.

In the application at issue, claim 99 discloses one specific A3 receptor antagonist compound, first disclosed on December 2, 1999. The compound of claim 99 is an improved compound in that it selectively binds to the adenosine A3 receptor with an affinity that is at least 10 times greater than its affinity for adenosine A1, A2a or A2b receptors (see Specification page 186, Table 15). Thus, the compound of claim 99 is a later-filed improvement over the genus of claims 1 and 4-6 in the '366 patent.

Applicants note the Examiner's assertion, without legal support, that "'later filed improvements' are not sufficient to overcome the instant rejection, as the compound as claimed in claim 99 is included in the genus of the '366 patent." However, the law contradicts such an assertion. For example, even if a case of

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Serial No.: 09/728,616
Filed : December 1, 2000
Page 26

prima facie obviousness were established, rebuttal evidence may consist of a showing that the claimed compound possessed unexpected properties. In re Dillon, 919 F.2d 688, 692-93 (Fed. Cir. 1990) Similarly, a later claimed improvement was held patentable even though it was encompassed by an earlier patented genus. In re Kaplan, 789 F.2d 1574 (Fed. Cir. 1986) In the instant case, it certainly was unexpected from the '366 genus of compounds that one specific compound, i.e., the one in claim 99, would have at least 10 times greater affinity for a receptor. Applicants note that the Examiner does not dispute the unexpectedness of the properties of the compound of claim 99. Instead, the Examiner merely makes an unsupported assertion that such improved properties are not enough. According to the law, however, the improved compound of claim 99 is patentable over a genus that encompasses it.

Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this double patenting rejection in its entirety.

Section 112 Paragraph 2 - Claims 117 and 118

On page 4 of the January 27, 2005 Office Action, the Examiner rejected claims 117 and 118 under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential elements.

In response, applicants have amended claims 117 and 118 to recite a method of treating "an inflammatory disease associated with an A3 adenosine receptor" and eliminate the qualification "associated with mast cell degranulation." It is known in the art that the A3 adenosine receptor has been implicated in inflammatory diseases (see Specification page 13, lines 22-27 and page 14, lines 16-20).

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Serial No.: 09/728,616
Filed : December 1, 2000
Page 27

Consequently, applicants contend that the claims as amended clearly describe the subject matter being claimed. Accordingly, applicants respectfully request that the Examiner reconsider and withdraw this rejection.

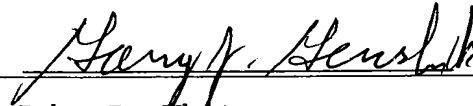
Conclusion

Applicants respectfully submit that the accompanying amendments and remarks serve to place all of the pending claims in condition for allowance.

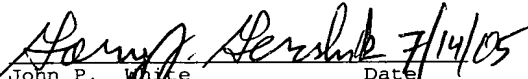
If a telephone interview would be of assistance in advancing prosecution of the subject application, applicants' undersigned attorney invites the Examiner to telephone him at the number provided below.

If any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 03-3125.

Respectfully submitted,



I hereby certify that this correspondence is being deposited this date with the U.S. Postal Service with sufficient postage as first class mail in an envelope addressed to:
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

 7/14/05
John P. White Date
Reg. No. 28,678
Gary J. Gershik
Reg. No. 39,992

John P. White
Registration No. 28,678
Gary J. Gershik
Registration No. 39,992
Attorneys for Applicants
Cooper & Dunham LLP
1185 Avenue of the Americas
New York, New York 10036
(212) 278-0400